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EXAMINER

BOWMAN, AMY HUDSON

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/073,123

Applicant(s)

LI ET AL.

Examiner

Amy H. Bowman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/12/2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a method of diagnosing cancer in a mammal comprising detecting and measuring the WIP1 gene copy number in a biological subject, classified in class 514, subclass 44.
- II. Claims 5 and 8, drawn to a method of inhibiting cancer or precancerous growth in a mammalian tissue comprising contacting the tissue with an antisense nucleotide that interacts with WIP1 DNA or RNA, classified in class 514, subclass 44.
- III. Claims 6 and 8, drawn to a method of inhibiting cancer or precancerous growth in a mammalian tissue comprising contacting the tissue with a ribozyme that interacts with WIP1 DNA or RNA, classified in class 514, subclass 44.
- IV. Claims 7 and 8, drawn to a method of inhibiting cancer or precancerous growth in a mammalian tissue comprising contacting the tissue with a nucleotide molecule that forms a triple helix with a WIP1-encoding nucleic acid that interacts with WIP1 DNA or RNA, classified in class 514, subclass 44.
- V. Claims 9-11, drawn to a method of monitoring the efficacy of a therapeutic treatment regimen comprising measuring WIP1 copy numbers and

comparing the gene copy number in samples, classified in class 514, subclass 44.

- VI. Claims 12-14, drawn to a method of diagnosing cancer in a mammal comprising measuring the level of WIP1 mRNA transcripts in a biological subject, classified in class 514, subclass 44.
- VII. Claims 16, 17 and 21, drawn to a method of inhibiting cancer or precancerous growth in a mammalian tissue comprising contacting the tissue with an inhibitor of WIP1 protein, wherein the inhibitor is an antibody that binds to WIP1 protein, classified in class 514, subclass 44.
- VIII. Claims 16, 18 and 21, drawn to a method of inhibiting cancer or precancerous growth in a mammalian tissue comprising contacting the tissue with an inhibitor of WIP1 protein, wherein the inhibitor is an antagonist to WIP1 protein, classified in class 514, subclass 44.
- IX. Claims 16, 19 and 21, drawn to a method of inhibiting cancer or precancerous growth in a mammalian tissue comprising contacting the tissue with an inhibitor of WIP1 protein, wherein the inhibitor is an antagonist to the 12-lipoxygenase activity of WIP1 protein, classified in class 514, subclass 44.
- X. Claims 16, 20 and 21, drawn to a method of inhibiting cancer or precancerous growth in a mammalian tissue comprising contacting the tissue with an inhibitor of WIP1 protein, wherein the inhibitor is a small molecule, classified in class 514, subclass 44.

- XI. Claims 22-24, drawn to a method of monitoring the efficacy of a therapeutic treatment regimen comprising measuring WIP1 mRNA or WIP1 expression levels, classified in class 514, subclass 44.
- XII. Claims 25-31, drawn to an isolated WIP1 gene amplicon, classified in class 514, subclass 44.
- XIII. Claim 32, drawn to a method of making a pharmaceutical composition, classified in class 514, subclass 44.
- XIV. Claims 33-35, drawn to a method of diagnosing cancer in a mammal comprising detecting WIP1 protein expression in a biological subject, classified in class 514, subclass 44.
- XV. Claims 36-38, drawn to a method of modulating WIP1 activities by contacting a biological subject from a region that is suspected to be precancerous or cancerous with a modulator of the WIP1 protein, wherein the modulator is a small molecule, classified in class 514, subclass 44.

Upon election of group I, II, III, IV, V, VI, VII, VIII, IX, X, XI, or XIV, applicant is required to further elect a specific species as explained below.

Claim 4 links the inventions of groups II, III and IV listed above. Claim 15 links the inventions of groups VII-X listed above. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 4 or 15. Upon the allowance of the linking claim(s), the restriction requirement as to the linked

inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

The invention of group I is unrelated to the invention of group II. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group II because group I is involved in diagnosing cancer in mammals, which is not an effect of group II. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group III because group I is involved in diagnosing cancer in mammals, which is not an effect of group III. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group IV because group I is involved in diagnosing cancer in mammals, which is not an effect of group IV. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group V because group I is involved in diagnosing cancer in mammals,

which is not an effect of group V. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have different modes of operations. The method of diagnosing cancer of group I involves detecting and measuring WIP1 gene copy numbers, whereas the invention of group VI is drawn to measuring the level of WIP1 mRNA transcripts. Each of these inventions involve a completely different measuring process with different method steps. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group VII because group I is involved in diagnosing cancer in mammals, which is not an effect of group VII. To search one of these inventions would not

necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group VIII because group I is involved in diagnosing cancer in mammals, which is not an effect of group VIII. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group IX because group I is involved in diagnosing cancer in mammals, which is not an effect of group IX. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group X because group I is involved in diagnosing cancer in mammals, which is not an effect of group X. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group XI because group I is involved in diagnosing cancer in mammals, which is not an effect of group XI. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group XII because group I is involved in diagnosing cancer in mammals,

which is not an effect of group XII. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group XIII because group I is involved in diagnosing cancer in mammals, which is not an effect of group XIII. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have different modes of operation. The method of diagnosing cancer of group I involves detecting and measuring WIP1 gene copy numbers, whereas the invention of group XIV is drawn to detecting WIP1 protein expression. Each of these inventions involve a completely different measuring process. To search one of these inventions would not necessarily return art against the other

invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group I is unrelated to the invention of group XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group I has a different effect than group XV because group I is involved in diagnosing cancer in mammals, which is not an effect of group XV. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of groups II, III, and IV, are unrelated to the inventions of groups VII, VIII, IX, and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have different modes of operation. The inventions are each drawn to a different method. Although each of the inventions is drawn to a method of inhibiting cancer or precancerous growth, the inventions of groups II, III and IV involve contacting tissue with a nucleotide molecule that interacts with WIP1 DNA or RNA, whereas the inventions of groups VII, VIII, IX and X are drawn to contacting tissue with an inhibitor of WIP1 protein. The method steps and mechanism involved in each of these methods are distinct from each

other. Searching for molecules that interact with DNA or RNA would not necessarily return art against inhibitors of WIP1 protein. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of groups II, III, and IV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have different modes of operation. Although each of the inventions is drawn to a method of inhibiting cancer or precancerous growth involving a molecule that interacts with WIP1 DNA or RNA, each of the inventions involves a different and distinct nucleotide molecule, sharing no common structural core. The antisense nucleotides, ribozymes, and triplexes instantly claimed are each structurally distinct and would interact with WIP1 DNA or RNA in different mechanisms. The method steps in each of these methods are distinct from each other. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of groups VII, VIII, IX and X are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not

disclosed as capable of use together and have different modes of operation. Although each of the inventions is drawn to a method of inhibiting cancer or precancerous growth involving an inhibitor or WIP1 protein, each of the inventions involves a different and distinct inhibitor, sharing no common structural core. The antibody, antagonist of WIP1 protein, antagonist of the 12-lipoxygenase activity of WIP1 protein, and small molecule instantly claimed are each structurally distinct and would interact with WIP1 protein in different mechanisms. The method steps in each of these methods are distinct from each other. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of groups II, III, IV, VII, VIII, IX and X are unrelated to the inventions of groups V and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Groups II, III, IV, VII, VIII, IX and X have a different effect than groups V and XI because groups II, III, IV, VII, VIII, IX and X are drawn to methods of inhibiting cancer or precancerous growth, which is not an effect of groups V and XI. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of groups II, III, IV, VII, VIII, IX and X are unrelated to the inventions of groups VI and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Groups II, III, IV, VII, VIII, IX and X have a different effect than groups VI and XIV because groups II, III, IV, VII, VIII, IX and X are drawn to methods of inhibiting cancer or precancerous growth, which is not an effect of groups VI and XIV. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of groups II, III, IV, VII, VIII, IX and X are related to the invention of group XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated WIP1 gene amplicon can be used to diagnose cancer, which does not involve inhibiting cancer. Each of these inventions involve separate considerations and would require a separate search. To search one of the inventions would not necessarily return art against the other.

The inventions of groups II, III, IV, VII, VIII, IX and X are unrelated to the invention of group XIII. Inventions are unrelated if it can be shown that they are not

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disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Groups II, III, IV, VII, VIII, IX and X have a different effect than group XIII because groups II, III, IV, VII, VIII, IX and X are drawn to methods of inhibiting cancer or precancerous growth, which is not an effect of group XIII. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of groups II, III, IV, VII, VIII, IX and X are unrelated to the invention of group XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Groups II, III, IV, VII, VIII, IX and X have a different effect than group XV because groups II, III, IV, VII, VIII, IX and X are drawn to methods of inhibiting cancer or precancerous growth, which is not an effect of group XV. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of groups V and XI are unrelated to the inventions of groups VI and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions,

or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Groups V and XI have a different effect than groups VI and XIV because groups V and XI are drawn to methods of monitoring the efficacy of a therapeutic regimen comprising measuring WIP1 copy numbers, WIP1 mRNA, or WIP1 expression levels, which is not an effect of groups VI and XIV. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of V and XI are related to the invention of group XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated WIP1 gene amplicon can be used to inhibit expression of WIP1, which does not involve monitoring the efficacy of a treatment regimen. Each of these inventions involve separate considerations and would require a separate search. To search one of the inventions would not necessarily return art against the other.

The inventions of groups V and XI are unrelated to the invention of group XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Groups V and

XI have a different effect than group XIII because groups V and XI are drawn to are drawn to methods of monitoring the efficacy of a therapeutic regimen comprising measuring WIP1 copy numbers, WIP1 mRNA, or WIP1 expression levels, which is not an effect of group XIII. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of groups V and XI are unrelated to the invention of group XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Groups V and XI have a different effect than group XV because groups V and XI are drawn to are drawn to methods of monitoring the efficacy of a therapeutic regimen comprising measuring WIP1 copy numbers, WIP1 mRNA, or WIP1 expression levels, which is not an effect of group XV. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group V is unrelated to the invention of group XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have different modes of operation. Although the inventions

of groups V and XI are drawn to methods of monitoring the efficacy of a therapeutic regimen, each of the methods involve separate and distinct mechanisms. The invention of group V involves measuring WIP1 copy numbers, whereas the invention of group XI involves measuring WIP1 mRNA or WIP1 expression levels. Each of these inventions involve separate and distinct measuring processes. The method steps in each of these methods are distinct from each other. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of VI and XIV are related to the invention of group XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated WIP1 gene amplicon can be used to inhibit expression of WIP1, which does not involve diagnosing a cancer in a mammal. Each of these inventions involve separate considerations and would require a separate search. To search one of the inventions would not necessarily return art against the other.

The inventions of groups VI and XIV are unrelated to the invention of group XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Groups VI and

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XIV have a different effect than group XIII because groups VI and XIV are drawn to methods of diagnosing cancer in a mammal, which is not an effect of group XIII. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The inventions of groups VI and XIV are unrelated to the invention of group XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Groups VI and XIV have a different effect than group XV because groups VI and XIV are drawn to methods of diagnosing cancer in a mammal, which is not an effect of group XV. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group VI is unrelated to the invention of group XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have different modes of operation. Although the inventions of groups VI and XIV are drawn to methods of diagnosing cancer in a mammal, each of the methods involve separate and distinct mechanisms. The

invention of group VI involves measuring the level of WIP1 mRNA transcripts, whereas the invention of group XIV involves detecting protein expression. Each of these inventions involve separate and distinct measuring processes. The method steps in each of these methods are distinct from each other. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

The invention of group XII is related to the invention of group XIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated WIP1 gene amplicon can be used to inhibit expression of WIP1, which does not involve making a pharmaceutical composition. Each of these inventions involve separate considerations and would require a separate search. To search one of the inventions would not necessarily return art against the other.

The invention of group XII is related to the invention of group XV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated WIP1 gene amplicon can be used to diagnose a disease, which does not involve modulating WIP1 activities. Each of these inventions involve

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separate considerations and would require a separate search. To search one of the inventions would not necessarily return art against the other.

The invention of group XIII is unrelated to the invention of group XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and have at least a different effect. Group XIII has a different effect than group XV because group XIII is drawn to a method of making a pharmaceutical composition, which is not an effect of group XV. To search one of these inventions would not necessarily return art against the other invention. To search more than one of these inventions would be burdensome and therefore restriction is proper.

Because these inventions are distinct for the reasons given above and the search required for each subgroup is not required for the others, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is

earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 2, 8, 10, 13, 21, 23, and 34 are directed to the following patentably distinct species of the claimed invention: breast tissue, lung tissue, prostate tissue,

ovarian tissue, and colon tissue. Each of the claimed tissues would express different tissue specific cancer genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755. The examiner can normally be reached on Mon-Fri 7:00 am – 4:30 pm.

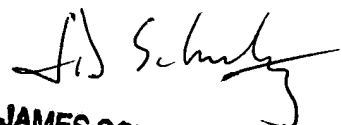
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman
Examiner
Art Unit 1635



JAMES SCHULTZ
PATENT EXAMINER